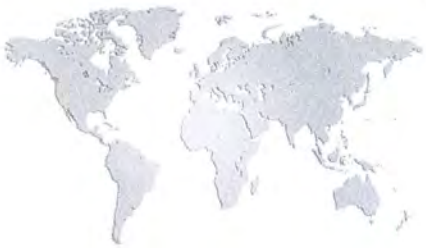
EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Medset Medizintechnik GmbH

Curslacker Neuer Deich 66, 21029 Hamburg, Germany

Certified location:

Curslacker Neuer Deich 66, 21029 Hamburg, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50271-Z6-00, the decision dated 2019-12-02 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-12-02 to 2024-05-26

Registration No.: 50271-16-06

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15 DEKRA DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-12-02
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-BS-295.10.02

84460

Annex to the EC Certificate No. 50271-16-06

Valid from 2019-12-02 to 2024-05-26

Revision status of the annex: 0 dated 2019-12-02

Devices/device categories included in the certificate:

Class II a:

- MD 1111
  - Software for
    - Long-term ECG PADSY-Holter 4.4
    - Rest ECG PADSY-ECG 4.4
    - Stress ECG PADSY-Ergo 2.14
    - Spirometry PADSY-Spiro 1.2
    - Ambulatory Blood Pressure Monitoring (ABPM) PADSY-RR 1.11

- MD 1302
  - Hardware for
    - Ambulatory Blood Pressure Monitoring (ABPM) Recorder SCANLIGHT
    - Spirometry Sensor Spirosound

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-12-02
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